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Dated 25 September 2003

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03SEP02 E745224-3 D02136
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Request for grant of a patent

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1-2 SEP 2002

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1.	Your reference	IT/RD/N12966
2.	Patent application number *(The Patent Office will fill this part)*	0220340.4
3.	Full name , address and postcode of the or of each applicant *(underline all surnames)*	Anson Medical Limited 67 Milton Park Abingdon Oxon OX 14 4RX United Kingdom
	Patents ADP number *(if you know it)*	08471640003
	If the applicant is a corporate body, give the country/state of its incorporation	United Kingdom
4.	Title of the invention	Flexible Stent-Graft
5.	Name of your agent *(if you have one)*	Williams, Powell & Associates
	"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*	4 St. Paul's Churchyard London EC4M 8AY
	Patents ADP number *(if you know it)*	08830310001

6.	If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number	Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7.	If this application is divided or otherwise derived from an earleir UK application, give the number and the filing date of the earlier application.	Number of earlier application	Date of filing *(day / month / year)*

8.	Is a statement of inventorship and of right to grant of a patent required in support of this request? *(answer 'Yes if:* *a) any applicant named in part 3 is not an inventor, or* *b) there is an inventor who is not named as an applicant, or* *c) any named applicant is a corporate body*	Yes

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	5
Claim(*s*)	DMC
Abstract	
Drawing(*s*)	2+2

10. If you are filing one of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/we request the grant of a patent on the basis of this application.

Signature [signature] Date 02 Sept 2002

12. Name and daytime telephone number of person to contact in the United Kingdom: Mr Lee Anderson 020 7329 4400

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Flexible Stent-Graft

This invention relates to implants for surgery to tubular vessels such as blood vessels, the trachea and bronchus and many parts of the gastro-intestinal tract but is currently of most benefit in surgery to arteries, more particularly those arteries which are susceptible to aneurysmal disease. Such arteries include the aorta, iliac and femoral arteries, although other sites are possible.

A number of stent-grafts for treating abdominal aortic aneurysms have been described or manufactured and many of the currently available commercial designs involve the combination of 'Z stents', similar to the Gianturco (Cook Inc, Indianapolis) and a conventional tubular vascular graft woven from polyester. 'Z stents' (Figure 2) are formed from metal wire such that the path of the wire lies on the surface of a cylinder and zig-zags repeatedly between the ends of the cylinder as the wire progresses around the circumference. Usually, the two ends of the wire are joined by welding, crimping or other means to provide a single resilient structure which is of low bulk and is capable both of being compressed radially and of expanding radially once compression forces have been removed.

The characteristics of the 'Z stent' can be adjusted for any given diameter by controlling the length of cylinder enclosed by the stent, the number of zig-zags made by the wire around the circumference of the cylinder and the physical characteristics of the wire. Further modifications and improvements to the basic design of the Z stent have been employed, generally to reduce stress at the Z bends in the construction. Figure 3 a, b, c and d illustrates variants of bend which have been employed. Struts in Z stents have also been modified, so that they are curved rather than straight, to permit attachments for barbs or to ease assembly of devices. The present invention applies equally to variants of Z stents as it does to the basic structure.

Two examples of stent-grafts employing 'Z stents" are the Medtronic 'Talent' device and the Cook 'Zenith" device. These implants employ multiple 'Z stents' which are sewn at intervals along the length of a tubular woven graft in such a way as to hold the graft open and to wedge the assembly within the artery in which it is deployed. The entire assembly can be compressed radially so that it will fit into a delivery catheter, providing the means for introducing the implant into the lumen of a patient's aorta via a minimal incision into the patient's femoral or iliac artery.

The 'Z stent' is not capable of being flexed along its central axis and is prone to collapse partially when it is flexed. For this reason, stent grafts comprised of 'Z stents' have limited, segmental flexibility, being inflexible in the regions of the stents and partially flexible at the gaps.

An alternative reinforcing structure to the Z-stent is a tube with perforated walls so that once radially expanded, the tube has roughly diamond-shaped perforations. Such reinforcements are used in the Anneurx product from Medtronic and the Cordis stent graft. The diamond mesh structures are generally stiffer than the wire zig-zags of the Z stent, limiting the flexibility of the overall structure in which they are used.

The present applicant has invented structures which are more flexible than the Z-stent or diamond mesh stent. Said structures can be used to support stent grafts and involve wire rings or helices supporting graft material. They allow stent grafts to be used in very much more tortuous vessels than designs using other reinforcements and provide a valuable clinical option.

The materials used for reinforcing structures in stent-grafts are typically metallic and include stainless steel, Elgiloy, titanium and shape memory alloys such as Nitinol. This latter class of material has been used successfully in both the thermal-effect and super-elastic conditions.

In use, stent grafts are compressed and packed into a delivery sheath which is typically $^1/_4$ of the diameter of the final device. Z-stents and diamond mesh stents can be compressed radially to this extent, giving rise to a small increase in their overall length.

By contrast, wire hoops are deformed into a saddle shape in which, if the wire is considered to be divided into quadrants, one pair of opposing quadrants is pulled above the plane of the hoop while the other pair of quadrants is pushed below the plane of the hoop.

Clinically, it is often difficult to assess the exact diameter of the vessel into which the stent graft is to be placed and clinicians will often select a stent graft which is larger in diameter than its intended implantation site by typically 15% to 20%, thereby ensuring that the implant is a firm fit. The consequence of this over-sizing is that the neck of the implant will remain partially deformed in a saddle shape, requiring a significant length of healthy tissue over which it is to be attached.

A useful compromise is achieved by combining the standard Z stent or diamond mesh stent with the wire ring or helical design. Such constructions can be easily envisaged, however, because the two types of support structure deform differently while being packed, it is difficult to combine both structures on a single device.

This disclosure describes a design technique which allows the two reinforcing structures to be combined in a single device while allowing the entire device to be compressed and packed in delivery sheaths which are typically $^1/_4$ of the diameter of the device

Figure 1 illustrates the preferred principle components of the design comprising:

The stent graft (1)
Reinforcing hoops (2)
Graft Fabric (3)

A change in diameter (4)
A spacing interval between hoop reinforcement and Z stent reinforcement (5)
A Z stent (6) comprising peaks (7) and troughs (8).

The embodiment shown in Figure 1 shows the combination of a Z-stent with hoop reinforcement in a graft which typically has a diameter in the range 10 mm to 50 mm Other applications may require implants as small as 3 mm and unusual anatomies may require implants as large as 60 mm. The change in diameter (4) is arranged so that the hoop reinforcements (2) can be deformed into a saddle shape so that they partially overlie the Z-stent section of the implant. Figure (1) illustrates the change in diameter increasing from the Z stent and this is the preferred embodiment. It is possible to construct an implant in which the change in diameter decreases from the Z stent, although packing is more difficult and the clinical benefits are reduced. The change in diameter is preferably between 3 and 10 times the thickness of the wall of the graft although if poorer performance can be tolerated, the range can be extended to 2 to 50 times the wall thickness.

The spacing interval (5) is preferably between 1/3rd and 1/6th of the diameter of the graft and can lie in the range 1/10th to 1/2 the diameter. Its function is to provide some articulation between the Z-stent and the rest of the implant as well as providing suppleness which allows the hoops to deform over the Z stent.

The design of the Z stent itself is optimised for combination with the hoop graft. Preferably, the stent has 6 peaks (7) so that when viewed from the Z stent end, peaks are orientated at 12 o'clock and 6 o'clock while troughs (8) are orientated at 3 o'clock and 9 o'clock. In this way, when the hoop is transformed into a saddle shape, its peaks coincide with the peaks of the Z stent and its troughs coincide with Z stent troughs. It will be seen that a Z stent having 2 + 4n peaks where n is an integer provides a series of stents with the properties as described. Practical stents have been manufactured where n=1, n=2 and n=3; the case where n=0 is equivalent to a hoop which has been deformed into a saddle shape.

The length separating the peak from the trough preferably lies in the range 5 mm to 20 mm for stent grafts used in the abdominal aorta or, more generally, lying in the range 1/4 to 1 times the diameter of the implant. Most preferably, the Z stent has as short a length as possible to provide the best articulation, although a variety of lengths may be appropriate for different clinical situations.

In one embodiment of the invention, the wire forming the Z-stent is run continuously from the Z stent and into the hoop supported section, permitting simplification in manufacture. Preferably, the path taken by the wire as it traverses the spacing interval (5) is oblique to the main axis of the tubular device.

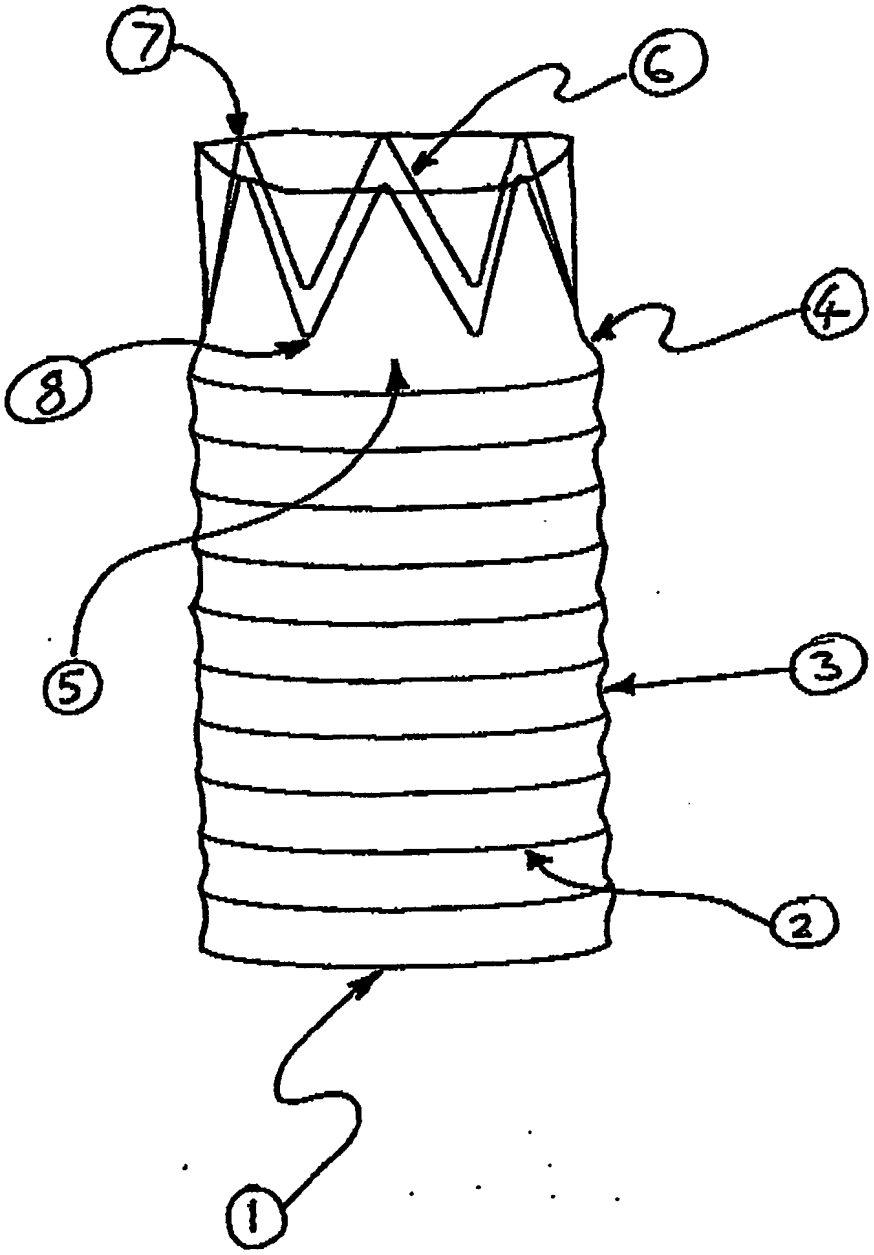

FIGURE 1

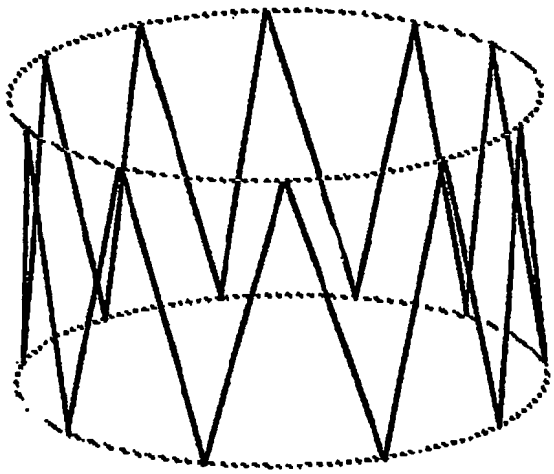

FIGURE 2

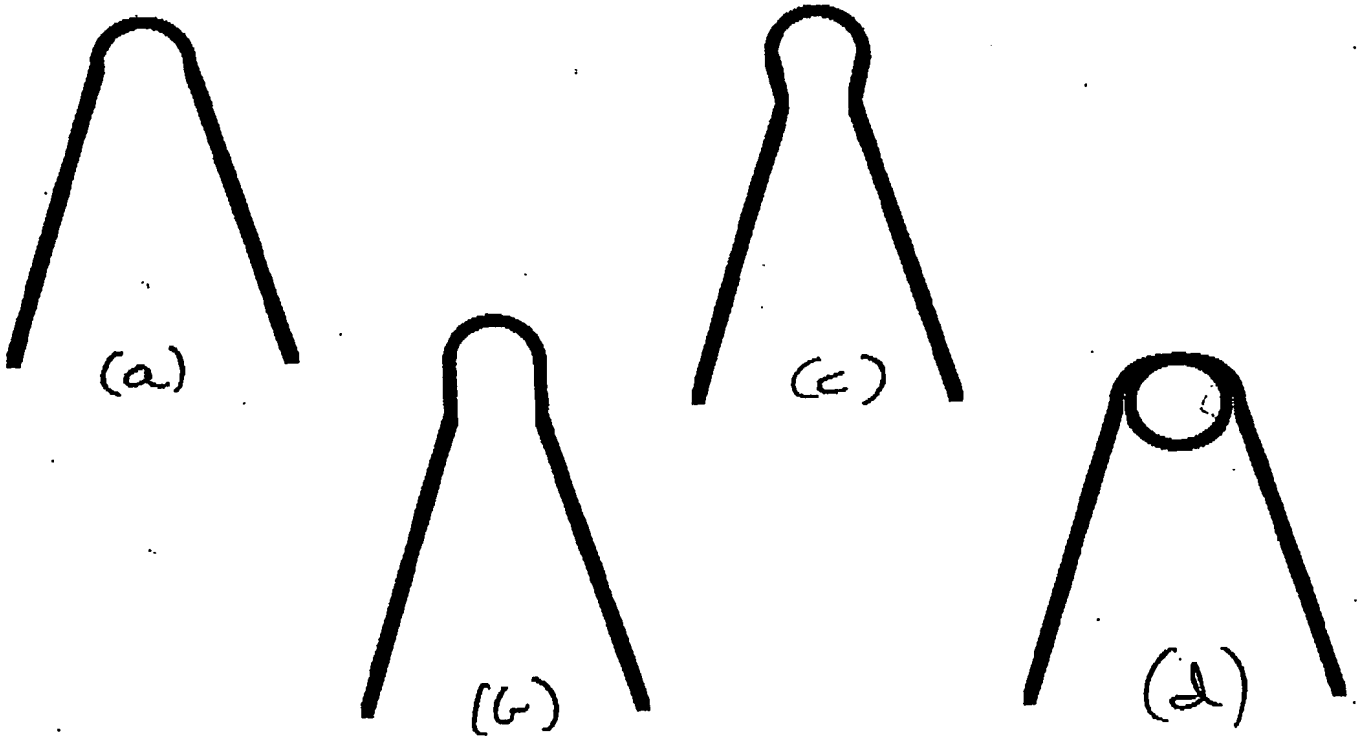

FIGURE 3

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